510(k) Summary

Date Prepared: December 20th, 2012

Submitter's Name / Contact Person

Submitter
Waters Medical Systems, LLC
2112 - 15th Street NW
Rochester, Minnesota 55901

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AUG 16 2013

General Information

Trade Name	PERF-GEN® Pulsatile Perfusion Solution
Common / Usual Name	Cold Storage Solution
Product Code	KDL
Classification Name	Set, perfusion, kidney, disposable
Classification Information	21 CFR 876.5880 Isolated kidney perfusion and transport system and accessories, Class II
Predicate Device	BELZER-MPS™, Trans-Med Corporation (K972066)

Device Description

The PERF-GEN® Pulsatile Perfusion Solution (PERF-GEN Solution) is a clear, sterile, non-pyrogenic, non-toxic solution for the in-vitro flushing and temporary continuous perfusion preservation of explanted kidneys. This solution has an approximate calculated osmolarity of 300 mOsm/kg, a sodium concentration of 100 mEq/L, a potassium concentration of 25 mEq/L, and a pH of approximately 7.4 at room temperature.

Intended Use / Indications

The PERF-GEN® Pulsatile Perfusion Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

Substantial Equivalence and Summary of Studies

The PERF-GEN Pulsatile Perfusion Solution device is substantially equivalent to the BELZER-MPS UW Machine Perfusion Solution. The PERF-GEN and BELZER-MPS solutions have an identical intended use, chemical composition and principle of operation. Both the subject and predicate device are sterile, non-pyrogenic, non-toxic, transparent solutions dispensed from a bag. Both solutions are sterilized by filtration and aseptically filled in sterile dispensing bags.

The technological difference between PERF-GEN Pulsatile Perfusion Solution compared to the predicate is related to the dispensing bag. The material used for the BELZER-MPS dispensing bags being not specified, it is likely that the bags of PERF-GEN and BELZER-MPS may differ in material. This technological difference has been evaluated

through biocompatibility, stability and chemical testing to ensure the possible bag material difference does not impact the specifications of the perfusion solution itself.

The biomaterial safety of the PERF-GEN Solution has been evaluated through ISO 10993 compliant testing, which included cytotoxicity test, acute systemic toxicity, hemocompatibility, genotoxicity, skin sensitization test in guinea pigs, and primary skin irritation. Results of this testing showed the PERF-GEN Solution is safe for the intended biocontact. Test results confirmed that the PERF-GEN Solution is non-cytotoxic, non-toxic, hemocompatible, non-genotoxic, non-sensitizing, and non-irritating.

Results of this stability study confirm that up to 1 year real-time aging at the recommended storage conditions and several months worst-case storage conditions do not affect the product specifications. The stability testing has showed that aging of test articles at the recommended storage conditions does not affect the product specifications for the PERF-GEN labeled with 1-year shelf life.

Chemical composition and properties of the PERF-GEN Solution and the predicate BELZER-MPS solution were compared by infrared, chromatography and conductivity measurements. The infrared spectra, the elution profiles and the ionic strengths of PERF-GEN and BELZER-MPS solutions were compared. The results of those chemical testing confirm that both the PERF-GEN solution and the predicate BELZER-MPS solution are chemically equivalent.

Results of evaluations did not raise any new questions of safety or effectiveness when compared to the predicate device and therefore the PERF-GEN Solution is substantially equivalent to the BELZER-MPS predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Waters Medical Systems, LLC
% Robert Warren
General Manager
2112 15th Street NW
Rochester, MN 55901

Re: K121736
Trade/Device Name: PERF-GEN® Pulsatile Perfusion Solution
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: KDL
Dated: August 1, 2013
Received: August 5, 2013

Dear Robert Warren,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121736

Device Name: PERF-GEN® Pulsatile Perfusion Solution

Indications for Use:

The PERF-GEN® Pulsatile Perfusion Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121736